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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,114	06/16/2000	Trudy H. Grossman	HMR2050	2671

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EXAMINER

LOEB, BRONWEN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	Applicant(s)	
	09/596,114	GROSSMAN ET AL.	
	Examiner	Art Unit	
	Bronwen M. Loeb	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13, 15 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 and 18 is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>20</u> . |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.   | 6) <input type="checkbox"/> Other: _____.   |

### **DETAILED ACTION**

This action is in response to the amendment filed 23 January 2003 in which claims 13, 15 and 18 were amended and claims 1-12, 14, 16, 17 and 28-49 were cancelled.

Claims 13, 15 and 18 are pending.

### ***Drawings***

1. The drawings filed on 16 June 2000 are acceptable subject to correction of the informalities indicated on the attached "Notice of Draftsperson's Patent Drawing Review," PTO-948, and the Examiner's objection below. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.
2. Figure 8 is objected to by the Examiner for referring to red text in the figure however the figure is in black and white thus there is no red.

### ***Response to Amendment***

3. The rejection of claims 15, 18, 44, 46 and 49 under 35 U.S.C. §112, first paragraph has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-12, 14, 28-43 and 45 under 35 U.S.C. §102(b) as being anticipated by Berg et al has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-7, 9, 10, 14, 28-36, 38, 40, 41 and 45 under 35 U.S.C. §102(e) as being anticipated by Reznikoff et al has been withdrawn in view of Applicant's amendment.

The rejection of claims 1, 2, 5-7, 14, 16, 17, 28, 29, 32-36, 38, 45, 47 and 48 under 35 U.S.C. §102(b) as being anticipated by Marsch-Moreno et al has been withdrawn in view of Applicant's amendment.

The rejection of claims 1, 2, 5, 14, 28, 29, 32, 34 and 45 under 35 U.S.C. §102(b) as being anticipated by Osusky et al (Gene (1994) 151:103-108; IDS Paper #12 reference AC) has been withdrawn in view of Applicant's amendment.

4. Claim 13 stands rejected under 35 U.S.C. §112, first paragraph for reasons of record and as further discussed below.

### ***Response to Arguments***

5. With regard to the rejection of claim 13 under 35 USC §112, first paragraph for lack of enablement, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that the specification provided detailed examples of the construction of the vectors claimed in Examples 1 and 2 on page 18 and 19. While this argument has been persuasive with respect to the vectors claimed in claims 15 and 18 in view of the telephone interview on 24 February 2003 (Paper #20), it is not persuasive with respect to pTRANS-SacB, claimed in claim 13. The specification does not provide sufficient guidance for one of skill in the art to reproduce pTRANS-SacB. Specifically,

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there is no teaching as to exactly where in the sequence of pGPS1 the moderate copy origin of replication is inserted, nor are there teachings about the specific sequence of the universal primers sites and exactly where in the sequence they are located, and there are no teachings about where exactly the sacB gene was inserted into the pGPS1 sequence. Thus, one of skill in the art would be unable to reproduce the exact claimed plasmid. A deposit will overcome the rejection under 35 USC §112, first paragraph for lack of enablement.

### ***Conclusion***

Claims 15 and 18 are allowed. Claim 13 is rejected. Claims 13, 15 and 18 are free of prior art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.  
Patent Examiner  
Art Unit 1636

April 6, 2003



JAMES KETTER  
PRIMARY EXAMINER